Department of Pesticide Regulation

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M E M O R A N D U M

TO: Tribufos, Risk Characterization Document File **HSM-02003**

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DATE: January 14, 2002

SUBJECT: TRIBUFOS MITIGATION

The Department completed the exposure assessment for the active ingredient DEF (tribufos) in 1995 (Formoli and Wang, 1995) and the risk characterization document (RCD) in November of 1998 (Lewis *et al*., 1998). Table 1 shows the acute exposure or absorbed daily dosage (ADD) and seasonal exposure or seasonal average daily dosage (SADD) that were estimated for DEF workers in the exposure assessment. Table 1 also shows the calculated margins of exposure (MOE) that are based on these exposure estimates and the toxicological endpoints determined in the RCD. A MOE of less than 100 is generally considered inadequate and requires mitigation. The RCD concluded that some field workers and handlers of DEF require mitigation. Mitigation measures were proposed in September of 1999 that required a 10-day REI for DEF (Andrews, 1999).

Table 1. Estimates of Exposure and Margins of Exposure (MOE) Calculated for Acute and Seasonal Exposure to DEF[a]

Work Task	ADD	SADD	Acute MOE[b]	Seasonal MOE[c]
	ug/kg/day	ug/kg/day		
Mixer/loader (aerial)	28.1	13.1	174	72
Pilot	33.2	15.5	148	61
Flagger	23.7	11.1	206	86
Mixer/loader (ground)	54.3	25.3	90	37
Applicator (ground)	4.4	2.1	1,114	463
Cotton Picker Operator[d]	94.3	44.0	52	22
Cotton Module Builder Operator[d]	29.8	13.9	164	68
Cotton Raker[d]	56.0	26.1	88	36
Cotton Tramper[d]	121.8	56.8	40	17

a. DEF Risk Characterization Document (Lewis *et al*., 1998).
b. Based on an adjusted acute NOEL for systemic effects of 4.9 mg/kg (rats- excessive salivation) (Lewis *et al*., 1998).
c. Based on an adjusted subchronic NOEL of 0.95 mg/kg (rabbits- muscle fasciculations, brain cholinesterase inhibition, and skin lesions). (Lewis *et al*., 1998).
d. Entering treated areas 7 days after an application.

In a meeting with the U.S. EPA and DPR in December of 1999, Bayer Corporation presented a primate dermal absorption study with DEF. Worker Health and Safety Branch (WH&S) reviewed the submitted dermal absorption study and initiated revising the exposure assessment to include the primate dermal absorption study. Table 2 shows the acute and seasonal exposures that were estimated for DEF workers in the revised exposure assessment. Table 2 also shows the calculated MOEs that are based on these revised exposure estimates and the same toxicological endpoints determined in the RCD. Based on the submitted dermal absorption study and revised exposure assessment, WH&S determined that an REI of 7 days was adequate to protect field workers and the existing personal protective equipment (PPE) on the label was adequate to protect handlers.

The registrant submitted a label amendment to show a 7-day entry restriction for harvest crew, however, the label provided an REI of 24 hours for other field activities. Therefore, in June of 2000, the Department registered the amended label on the basis that a use permit be issued to require a 7-day REI for the year 2000 use season, until an acceptable labeling is provided (Patterson, 2000). Subsequently, the Pesticide Enforcement Branch issued a use permit condition for the year 2000 use season, requiring a 7-day entry restriction to fields treated with DEF (Duncan, 2000).

Table 1. Estimates of Exposure and Margins of Exposure (MOE) Calculated for Acute and Seasonal Exposure to DEF[a]

Work Task	ADD	SADD	Acute MOE[b]	Seasonal MOE[c]
	ug/kg/day	ug/kg/day		
Mixer/loader (aerial)	4.6	2.1	1070	452
Pilot	5.1	2.4	960	396
Flagger	4.4	2.1	1110	452
Mixer/loader (ground)	8.5	4.0	580	237
Applicator (ground)	0.7	0.3	7000	3170
Irrigators and weeders	11.3	5.3	430	179
Cotton Picker Operator[d]	5.0	2.3	980	413
Cotton Module Builder Operator[d]	1.9	0.9	2580	1060
Cotton Raker[d]	3.4	1.6	1440	594
Cotton Tramper[d]	8.3	3.9	590	244

a. DEF Risk Characterization Document (Lewis *et al*., 1998).
b. Based on an adjusted acute NOEL for systemic effects of 4.9 mg/kg (rats- excessive salivation) (Lewis *et al*., 1998).
c. Based on an adjusted subchronic NOEL of 0.95 mg/kg (rabbits- muscle fasciculations, brain cholinesterase inhibition, and skin lesions). (Lewis *et al*., 1998).
d. Entering treated areas 7 days after an application.

Currently, there are two products registered in California that contain DEF as an active ingredient (DEF® 6 Emulsifiable Defoliant, EPA Registration # 3125-282-AA and Folex® EC Cotton Defoliant, EPA Registration # 264-498-AA). Both product labels have recently been amended to show the 7-day REI. The 7-day REI on the labels negates the need for any mitigation.

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Refernces:

Andrews, C. 1999. Mitigation proposal for tribufos (DEF), Memorandum of September 8 to P.H. Gosselin, Worker Health and Safety Branch, DPR.

Formoli, T.A. and Wang, R.G.M. 1995. Estimation of exposure of persons in California to pesticide products that contain tribufos (DEF). Worker Health and Safety Branch, DPR.

Duncan, D. 2000. Label interpretations and permit conditions for the use of s,s,s-tributyl phosphorotrithioate (Tribufos), Letter of June 22 to County Agricultural Commissioners, Pesticide Enforcement Branch, DPR.

Lewis, C. M. 1998. S,S,S-tributyl phosphorotrithioate (DEF) risk characterization document, Medical Toxicology Branch, DPR.

Patterson, G. 2000. Registration of DEF. Memorandum of June 15 to registration file. Division of Registration and Health Evaluation, DPR.